Prospective randomized controlled clinical study comparing two types of two-piece dental implants supporting fixed reconstructions - results at 1 year of loading

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Abstract: OBJECTIVES To analyze clinical, esthetic, radiographic, and prosthetic outcomes of implants and implant-supported reconstructions using two types of dental implants with non-matching implant abutment junctions. MATERIALS AND METHODS A total of 64 patients in need of dental implant therapy with fixed reconstructions were consecutively enrolled. They were randomly assigned to either one of two implant systems (S1: Astra Tech Osseospeed and S2: Straumann Bone Level). Baseline (day of loading) and 1-year measurements included demographics, radiographic, clinical, biologic, prosthetic, and esthetic outcomes. All data were analyzed at the patient level and at the implant level. The nonparametric Mann-Whitney U-test was used to detect differences in continuous variables between two independent groups. RESULTS Ninety-seven implants (S1 = 54, S2 = 43) were placed and loaded with fixed reconstructions in 64 patients. No implant was lost during the 1-year observation period resulting in a 100% survival rate for both implant systems. At the patient level, the mean marginal bone level at implant insertion was -1.30 mm (SD ± 1.00 mm) for S1 and -1.26 mm (±1.22 mm) for S2 (negative values indicating bone levels coronal to the implant shoulder). At the time of loading, these distances measured 0.29 mm (±0.44 mm) for S1 and 0.22 mm (±0.43 mm) for S2. At the 1-year follow-up, these distances were 0.37 mm (±0.39 mm) for S1 and 0.39 mm (±1.02 mm) for S2. Technical complications of the reconstructions only occurred in Group S1, with a rate of 12% (patient level) ($P > 0.05$). Biologic complications were observed at a rate of 6% (S1) and 3.2% (S2) at the patient level ($P > 0.05$). CONCLUSIONS Both implant systems revealed 100% survival rates and minimal changes of the marginal bone levels during 1 year of loading. Few technical and biologic complications occurred. Therefore, both implant systems can be recommended for fixed reconstructions.

DOI: https://doi.org/10.1111/clr.12721

Prospective randomized controlled clinical study comparing two types of two-piece dental implants supporting fixed reconstructions – results at one year of loading.

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Running title: Randomized controlled study comparing two-piece implant systems

Key words: "dental implants", "fixed, partial, denture", "x-ray", and "survival"

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Abstract

Objectives: To analyze clinical, esthetic, radiographic and prosthetic outcomes of implants and implant-supported reconstructions using two types of dental implants with non-matching implant abutment junctions.

Materials and methods: 64 patients in need of dental implant therapy with fixed reconstructions were consecutively enrolled. They were randomly assigned to either one of two implant systems (S1: Straumann Bone Level and S2: Osseospeed Astra Tech). Baseline (day of loading) and one-year measurements included demographics, radiographic, clinical, biological, prosthetic and esthetic outcomes. All data were analyzed at the patient and at the implant level. The non-parametric Mann-Whitney-test was used to detect differences in continuous variables between two independent groups.

Results: Ninety-seven implants (S1=54, S2=43) were placed and loaded with fixed reconstructions in 64 patients. No implant was lost during the one-year observation period resulting in a 100% survival rate for both implant systems. At the patient-level, the mean marginal bone level at implant insertion was -1.30mm (SD ± 1.00mm) for S1 and -1.26mm (± 1.22mm) for S2 (negative values indicating bone levels coronal to the implant shoulder). At the time of loading, these distances measured 0.29mm (± 0.44mm) for S1 and 0.22mm (± 0.43mm) for S2. At the one-year follow up, these distances were 0.37mm (± 0.39mm) for S1 and 0.39mm (± 1.02mm) for S2. Technical complications of the reconstructions only occurred in group S1, with a rate of 12% (patient-level)

(p>0.05). Biological complications were observed at a rate of 6% (S1) and 3.2% (S2) at the patient-level (p>0.05).

Conclusions: Both implant systems revealed 100% survival rates and minimal changes of the marginal bone levels during one year of loading. Few technical and biological complications occurred. Therefore, both implant systems can be recommended for fixed reconstructions.

Introduction

Dental implants are a viable treatment option to restore function and esthetics in the oral cavity. Over time, the numbers of implants and implant systems available on the market greatly increased. A clinician today is confronted with hundreds of possible implant systems and designs to select from. Obvious factors, such as surgical and prosthetic options, survival and success rates as well as overall costs, form the basis for the clinician's decision-making for the choice of an implant system (Antonarakis, et al. 2014, Vogel, et al. 2013, Zitzmann, et al. 2013).

The main differences among the available systems consist in the variety of implant designs and surfaces. In general, two main implant types are available; one-piece and two-piece implants. For the latter, two types exist: i) with matching implant-abutment junction; ii) with non-matching implant abutment junction. The design of the implant-abutment junction appears to be a critical factor with respect to the initially occurring marginal bone loss following implant placement (Cardaropoli, et al. 2006, Prosper, et al. 2009). Long-term results of clinical studies demonstrated favorable maintenance of the marginal bone level with initially minimal bone loss for implants with a non-matching implant-abutment (Astrand, et al. 2004, Gotfredsen 2004, Palmer, et al. 2000).

These more favorable (in terms of the initial marginal bone loss) results using a non-matching implant-abutment junction design may in part be explained by an increased distance between the bone and the microgap and fewer micromovements due to the internal conical connection between implant

and abutment (Abrahamsson, et al. 2003, Hansson 2000, Hansson 2003, Hermann, et al. 2001, Jung, et al. 2008, Rasmusson, et al. 2001). These observations were confirmed by preclinical studies evaluating the influence of matching and non-matching implant abutment junctions (Broggini, et al. 2006, Heitz-Mayfield, et al. 2013, Hermann, et al. 1997). Currently, several dental implant systems offer two-piece dental implants with a non-matching implant-abutment junction. Still, clinical data are scarce comparing two of these implant systems in a prospective controlled clinical study.

The aim of this present study was therefore, to analyze clinical, esthetic, radiographic and prosthetic outcomes of two types of dental implants with non-matching implant-abutment junctions loaded with fixed implant-borne reconstructions.

Materials and methods

Study design

This study was designed as a randomized controlled clinical trial at the Clinic of Fixed and Removable Prosthodontics and Dental Material Science Center of Dental Medicine, University of Zurich, Switzerland. The study protocol was approved by the local ethical committee. Sixty-four patients in need of dental implant therapy with fixed dental prostheses were consecutively enrolled in the study after signing the informed consent.

Enrolled patients were randomly allocated using a computer-generated randomization list to receive implants from one of the two systems (S1=Astra Tech OsseoSpeed®; ASTRA TECH Implant System, DENTSPLY Implants, Mölndal, Sweden; S2= Straumann Bone Level® Implants; Institut Straumann AG, Basel, Switzerland).

The following inclusion criteria were applied:

- patients had to be healthy and of legal age
- no local jaw pathology
- no periodontal disease (periodontal probing depths <4mm)
- good oral hygiene (full mouth plaque index <25%) (O'Leary, et al. 1972)
- adequate control of inflammation (full mouth bleeding on probing <25%) (Ainamo & Bay 1975)
- no restrictions were made with respect to the location of the implant(s) (upper/lower jaw, anterior/posterior sites)

- implant therapy with fixed reconstructions

No restrictions were made in terms of the need for bone regeneration prior to or simultaneously with implant placement. Patients not meeting the inclusion criteria were not considered for the study.

Surgical procedure

All surgical procedures were performed in accordance to the standard protocols of the respective implant systems provided and based on the manufacturers' recommendations. Generally, the implants were placed with the implant shoulder at the bone crest in both groups. Some implants were placed, for prosthetic reasons, with an increased sink depth (i.e. the implant shoulder was placed below the bone crest). Depending on the bony conditions and the location, the following implant types, lengths and diameters were used: S1 with diameters varying between 3.0 and 5.0 mm and lengths between 6 and 16 mm and S2 with diameters varying between 3.3 and 4.8 mm and lengths between 6 and 14 mm. All implants had a medium rough surface and a non-matching implant-abutment junction.

In case of a dehiscence or a fenestration defect, a guided bone regeneration (GBR) procedure was applied. GBR was performed using demineralized bovine bone mineral (DBBM) (Bio-Oss Spongiosa®; Geistlich Pharma AG, Wolhusen, Switzerland). The DBBM was either covered with a resorbable (Bio-Guide®, Geistlich Parma AG) or a non-resorbable membrane (Gore-Tex®; W.L. Gore & Assoc., Flagstaff, AZ, USA). In some cases a synthetic biphasic calcium phosphate (BCP) consisting of a mixture of 60% hydroxyapatite

and 40% of beta-tricalcium phosphate (Straumann Bone Ceramic®, Institut Straumann AG, Basel, Switzerland) covered with a synthetic bioresorbable polyethylene glycol (PEG) hydrogel membrane (MembraGel®, Institut Straumann AG, Basel, Switzerland) was applied. The materials used depended on the clinical situation and the surgeon’s preference.

At the end of the surgery a standardized peri-apical x-ray was taken. No restrictions were made with respect to the healing protocol (submerged vs. transmucosal healing) and the healing time before loading with the final reconstruction.

Prosthetic procedure

The prosthetic procedures were performed according to the guidelines of the individual implant systems. Screw-retained or cemented reconstructions were used based on the clinical situation and the clinician's expertise.

The day of the insertion of the final prosthesis was considered as baseline (TP1). At the time of the baseline examination, all patients entered an individually designed maintenance program, which included regular dental hygiene sessions. One year after baseline examination, all patients were recalled for a one-year follow-up clinical examination.

Outcome measures

Implant and reconstruction survival rates as well as technical and biological complication rates (adverse events) for implants and reconstructions were calculated at the implant and patient level.

Radiographic assessment

Standardized x-rays were made immediately after implant insertion, at baseline and at the one-year follow-up. The intraoral radiographs were obtained using a paralleling technique with Rinn-holders and analogue films (Kodak Ektaspeed Plus, Eastman Kodak and Co., Rochester, NY, USA). The x-rays were first digitalized and the marginal bone levels assessed at a 10x to 15x magnification using an open-source software (Image J; National Institutes of Health, Bethesda, MD, USA). The known distance between two implant threads was used to calibrate and determine the exact magnification of the individual images. The marginal bone level was examined at both the mesial and distal implant surfaces. This was done by measuring the distance between the flat top of the implant shoulder and the bone crest using a scale divided into 0.1 mm steps (= distance implant to bone, DIB). The marginal bone levels were measured at three time-points: 1. implant placement (TP0), 2. insertion of final prosthesis (TP1), 3. one-year follow-up examination (TP2). Marginal bone level changes were then calculated as differences between the three time-points.

In addition, all implant-supported cantilever fixed dental prostheses (ICFDPs) were compared to non-cantilever fixed dental prostheses (nICFDPs) in both groups in order to evaluate the influence of the type of reconstruction on marginal bone level changes. Furthermore, the crown to implant ratios were measured at TP1 and TP2 and compared for both implant systems.

Clinical and esthetic parameters

Clinical measurements were taken at six sites per implant (mesiobuccal, buccal, distobuccal, distolingual, lingual, and mesiolingual), at the neighbouring teeth/implant(s) and the contralateral tooth or implant using a periodontal probe (UNC-15, Hu-Friedy, Chicago, IL, USA). The parameters measured and the chronology of measurements were as follows:

Probing pocket depth (PPD, mm), bleeding on probing (BOP, %), plaque control record (PCR,%) (O'Leary, Drake & Naylor 1972), recession (REC, mm) and the width of keratinized tissue on the buccal site of each implant (KMb, mm). Esthetic parameters included the papilla contour measurements mesially and distally (Jemt mes/Jemt dist,) (Jemt 1999) at the implant site(s). In addition, the papilla height (mesial papilla (PHm, mm), distal papilla (PHd, mm), and crown height (CH, mm) were assessed. The papilla height covered the distance between the tip of the papilla and the highest point of the incisal edge. The crown height was defined as the distance between the most apical point of the gingiva recession and the incisal edge. The thickness of the gingiva/mucosa was measured with an endodontic instrument (Hedstrom files #15, Dentsply Maillefer, Ballaigues, Switzerland) at a level 1mm below the margo mucosae (GT,mm). The changes for all biological and esthetic outcomes were evaluated statistically between TP1 and TP2 in both groups.

Statistical analysis

Data were recorded in Microsoft Excel spreadsheets (Microsoft" Corporation, Redmond, WA, USA) and analyzed in SPSS Version 19 (IBM; SPSS Inc., Chicago,

IL, USA; SPSS" Statistics; SPSS Inc.). Descriptive statistics such as mean, median, standard deviation, interquartile range, minimum and maximum as well as absolute and relative frequencies were computed at the implant and patient level. For the implant-level analysis, one implant per patient was randomly selected for descriptive statistics. Chi2 and Fisher exact tests evaluated association between two discrete variables. On patient-level, the non-parametric Mann-Whitney test was used to detect a difference in a continuous variable between two independent groups (comparison S1 to S2). In addition, the non-parametric paired Wilcoxon test assessed the influence of time between two continuous variables (analysis of the time-points), whereby these were evaluated non-parametrically by means of a Spearman correlation. Both a log-rank test helped to analyze the survival rate of the implants on patient and implant level. Finally, results of the statistical analysis with p-values smaller than 0.05 were considered statistically significant.

Results

Demographic data

A total number of 64 patients (33 in group S1: 17 females and 16 males with 54 implants; 31 in group S2: 21 females and 10 males with 43 implants) were included in the study. The mean age for group S1 was 55.0 years (SD±11.6 years) and 54.3 years (SD±16.1 years) for group S2. All implants were inserted between February and December 2009. This included 68 implants placed in the upper jaw (S1: 34, S2: 34) and 29 in the lower jaw (S1: 20, S2: 9).

The mean time between implant placement (TP0) and the insertion of the final prosthesis (TP1 – baseline) was 9.14 months for group S1 (SD± 4.47, range: min. 2.46 to max. 21.62 months) and 10.52 months for group S2 (SD± 4.61, range: min. 3.75 to max. 20.96 months).

The mean time between prosthesis insertion and the one-year follow-up was 15.57 months for group S1 (SD± 4.05, range: min. 8.21 to max. 19.94 months) and 15.80 months for group S2 (SD± 4.07, range: min. 10.55 to max. 23.55 months).

The prosthetic reconstructions (all of them fixed) included single crowns, splinted single crowns, fixed dental prostheses (FDPs) and implant-supported cantilever fixed dental prostheses (ICFDPs). An overview is given in Table 1.

None of these demographic data did reveal any statistically significant differences between the two groups ($p>0.05$).

Survival rate and success rates

No implants were lost during the one-year observation period resulting in a 100% survival rate for both implant systems.

Implant-level analysis for adverse technical and biological events

Technical complications occurred for seven S1 implants, but not for S2 implants. One implant/reconstruction (S1) was affected by three technical events (loosening of screw, a fractured screw and a chipping). Another implant was not restored following the fracture of a screw, which could not be removed. Therefore, the implant was left as a submerged sleeper. Further technical events included loosening of screws (n=4), fractured screws (n=5) and chipping of veneering ceramics (n=2).

A total number of five biological events occurred. This included: mucositis with BOP at all six sites around the implant (S1 n= 2; S2 n=1); peri-implantitis with bone loss ≥ 2mm (S1 n=2).

In total, a success rate of 81.5 % for S1 and of 95.3% for S2 could be reported on implant-level.

Patient-level analysis for technical and biological events

At the patient level, four technical events occurred on four implants (all S1 implants). In addition, two biological events were observed in the S1 group (BOP at all six sites around one implant, and bone loss ≥ 2mm at another implant) and one in the S2 group (BOP at all six sites around the implant). The differences between the two groups were not statistically significant neither for

technical (p=0.077) nor biological adverse events (p=0.591). At this level, the success rate was 81.8% for S1 and 96.8% for S2.

Radiographic results

Implant-level analysis

The relative distances between the implant shoulder and the bone crest ranged between -4.01mm and 0.59mm (S1) and between -4.92mm and 0.65mm (S2). Negative values indicated that the implant shoulder was located more apically relative to the bone crest. The mean relative distance between the implant shoulder and the bone crest at implant placement was -1.07mm (SD ± 0.94mm) for S1 and -1.21mm (± 1.13mm) for S2. At the time of loading, this distance measured 0.39mm (± 0.53mm) for S1 and 0.21mm (± 0.40mm) for S2. At the one-year follow-up, these distances were 0.49mm (± 0.62mm) for S1 and 0.34mm (± 0.88mm) for S2.

A full overview is given in Table 2.

Patient-level analysis

The mean relative distance between the implant shoulder and the bone crest at implant placement was 1.30mm (SD ± 1.00mm) for S1 and -1.26mm (± 1.22mm) for S2. At the time of loading these distances were 0.29mm (± 0.44mm) for S1 and 0.22mm (± 0.43mm) for S2. At the one-year follow-up, these distances were 0.37mm (± 0.39mm) for S1 and 0.39mm (± 1.02mm) for S2. The median marginal bone levels at the one-year follow-up were statistically significantly different between the two groups and in favor of group S2

(p=0.008). The median bone level changes were statistically significant for both groups (p<0.001) between implant placement and prosthesis insertion, but not between prosthesis insertion and the one-year follow-up (S1 p=0.342; S2 p=0.532). A full overview is given in Table 2.

No statistically significant influence was observed in terms of median marginal bone level changes (S1: p=0.331, S2: p=0.919) comparing ICFDPs (S1 n=6; S2 n=11) to nICFDPs (S1 n=27; S2 n=20). Consequently, there was no association between either treatment group S1 and S2 or the type of reconstruction on bone level (p=0.084).

The crown to implant ratio did not demonstrate any statistically significant differences between the two groups and ranged from 1.09 and 1.19 (p>0.05).

Clinical and esthetic outcome measures

Implant-level analysis:

The results of the clinical parameters (PPD, BOP, PII, REC, KMb) are reported in the Table 3a. Table 3b shows the esthetic parameters (Jemt, CH, PHm, PHd, GT) for the different time-points.

Patient-level analysis:

No statistically significant differences were observed between the groups and between prosthesis insertion and the one-year follow-up with respect to clinical and esthetic parameters (p>0.05). The papilla at the mesial (Jemt mes) (S1: TP1:1.72 (SD ±0.68) / TP2:1.84 (±0.69); S2 TP1: 1.85 (±0.72) / TP2: 2.00 (±0.73)) and distal (Jemt dist) aspect (S1: TP1: 1.46 (±0.58) / TP2: 1.52

(±0.51); S2: TP1: 1.32 (±0.75) / TP2: 1.58 (±0.77)) increased in both groups, but not statistically significantly ($p>0.05$). The crown height (CH) demonstrated a slight tendency for an increase in both groups: S1 (TP1: 9.79 (± 1.33); TP2: 9.88 (± 1.49)) ($p=0.694$) and S2 (TP1: 9.74 (± 1.77); TP2: 10.03 (± 2.09)) ($p=0.124$). All data are displayed in Tables 3c & 3d.

Discussion

The current study revealed a 100% implant survival rate during the first year of loading for both implant types with a non-matching implant-abutment junction. At the one-year follow-up, no significant differences were observed in terms of mean marginal bone levels between the two systems on patient level. A higher rate of technical and biological complications was observed for S1 during the one-year follow-up.

Dental implants demonstrate long-term survival rates of more then 90% over 5 and 10 years (Buser, et al. 1996, Gotfredsen 2012, Jemt 2008, Jung, et al. 2013). These results were reported in private practice settings, specialized clinics, and university settings (Buser, et al. 2012, Jemt & Lekholm 2005, Krennmair, et al. 2010, Schneider, et al. 2012). Only a few implant systems reported long-term clinical data on implant and prosthesis level.(Jung, et al. 2012, Pjetursson, et al. 2012). The outcomes of the present study confirm these results on a short-term basis with no implants lost during the one-year follow-up. Both systems, S1 and S2 rendered similar outcomes with respect to the survival rate and demonstrated that they can be used on a daily basis with predictable outcomes supporting fixed reconstructions.

Both implant types are designed to be placed with the implant shoulder at the level of the surrounding bone. In the present study, the relative distances between the implant shoulder and the bone crest ranged between -4.92mm and

0.65mm. This indicated that in many cases, implants were placed below the bone crest, mainly for prosthetic reason. At time of implant placement (TP0), S2 implants were placed deeper with respect to the bone crest than were S1 implants. In a dog study, it was shown that a more vertical sink depth at time of implant placement influences the changes of the marginal bone levels within the first 6 months (Jung, Jones, Higginbottom, Wilson, Schoolfield, Buser, Hammerle & Cochran 2008). These early biologic remodeling processes were radiographically documented in the present study. Radiographs were taken at implant placement (TP0), after insertion of final prosthesis (TP1 – baseline) and after one year of functional loading (TP2). The distances between the shoulder of the implants and the marginal bone levels changed from implant placement to baseline and from baseline to one year later. These bone remodeling processes observed between baseline and one year of functional loading may not be exclusively considered a physiologic adaptation, but may reflect adapting changes elicited mainly due to bacterial infection as assumed in the Consensus Report of the Senventh European Workshop of Periodontology (Lang, et al. 2011). However in contradiction to the mentioned consensus report, also mechanical loads could play a role in the long-term bone level changes around dental implants (Marcelis, et al. 2012). In the present study, marginal bone level changes from implant placement to the one-year follow-up differed between the two implant systems. S2 implants demonstrated less marginal bone loss between implant placement and loading with the final prosthesis. S1 implants implant lost less marginal bone between loading and the one-year follow-up. Overall, for both systems, the biologic adaptation continued during the 1-year

observation period. At the one-year follow-up, no significant differences were observed in terms of mean marginal bone levels between the two systems on the patient level. The marginal bone levels observed in the present study are consistent with those reported in previous clinical studies for both systems (Buser, et al. 2009, Gulje, et al. 2013, Hammerle, et al. 2012). For S1 implants, a mean marginal bone level at the time of loading of 0.1mm (SD ± 0.04mm) below the reference point was reported in a clinical study with 36 consecutive patients. Fifty-three implants were inserted in combination with an osteotome sinus floor elevation technique. Abutment connection was performed 3 to 4 month later and implants loaded one month later with prosthetic reconstructions. One year later, the corresponding mean marginal bone level was 0.5mm (± 0.06mm) (Fermergard & Astrand 2008). This is in agreement with the outcomes of a multicenter study, reporting minimal marginal bone level changes from implant placement to 3 and 12 months and a marginal bone level slightly below the implant shoulder at the last follow-up(Donati, et al. 2008). Comparatively, in the present study, mean marginal bone levels were 0.29mm (± 0.44mm) at the time of loading and 0.37mm (± 0.39mm) one year later. Data on S2 implants were reported in a randomized, controlled multi-center clinical trial. In that study, marginal bone loss was compared differentiating between implants in two healing modes (submerged versus transmucosal healing). One hundred seventy-seven fixed reconstructions were seated 6 month after implant placement. Reported marginal bone level changes were -0.47mm for the submerged group and -0.48mm for the transmucosal group (Hammerle, Jung, Sanz, Chen, Martin, Jackowski & Multicenter study 2012).

Technical complications of the fixed reconstructions were only observed in one of the two groups (S1). The most common complications were screw loosening and fractures of screws. On the implant level, 7 of 54 S1 Implants (13%) showed technical complications. However, one single patient suffered from a fractured screw (single crown at position 36) and two screw loosenings (FDP at position 46-x-44). The screws were retightened, but then fractured at a later time-point. Moreover, a major ceramic chipping was observed for the same FDP. This relatively high rate of technical complications in one single patient may be explained by the fact that this patient reported bruxism during the night. Based on a recently published systematic review (Manfredini, et al. 2014), implant therapy in patients with bruxism does not lead to more biological, but more technical complications on the reconstruction level. Additionally, two screw fractures occurred in a FDP (12-x-x-22), in a single crown (25) supported by a CAD/CAM abutment, whereas a screw loosening was observed at a single crown (25). This in turn, resulted, on the patient level, in 4 of 33 S1 implants (12%) with technical complications. In a clinical study using S1 implants, patients received implant-supported yttria-stabilized tetragonal zirconia polycrystal fixed dental prostheses (Y-TZP FDPs). At the 3-year follow-up, all FDPs were in use and none of the reconstructions had fractured. However, superficial chip-off fractures of the veneering porcelain were observed in 14% (14 units in 7 patients) at 12 month (Larsson, et al. 2010). For FDPs made of porcelain-fused to metal, technical complications are reported at a level of 16% at 5 years for this specific implant system (Wennstrom, et al. 2004). For S2 implants, no long-

term data are available. Short-term clinical studies, however, report abutment screw loosening occurring at a rate of 18.2% in one study and just one porcelain fracture on one single crown during a 15-month follow-up period in 60 patients with 60 implants (Barter, et al. 2012, Santing, et al. 2013).

In the present study, two biological events were observed in the S1 group (6%) and one biological event in the S2 group (3.2%) upon patient-level analysis during the one-year loading period. This included two implants in each group with a mucositis (BOP at all six sites around the implants) and one implant with bone loss >2mm (S1). The 6th European Workshop on Periodontology defined mucositis as an inflammatory lesion that affects the soft tissue, whereas peri-implantitis also affects the supporting bone, and in its final stages leads to implant loss. It also confirmed that both mucositis and peri-implantitis are of infectious origin (Figuero, et al. 2014, Lindhe, et al. 2008). The prevalence of peri-implant infections varies. In a study with 216 patients, 73% of the patient showed a peri-implant mucositis and 56% showed a periimplantitis (Roos-Jansaker, et al. 2006). More recent data of 99 patients with 351 implants showed BOP and bone loss with ≥ 3 mm in 11.3% of the patients, whereas 47,1% of the patients had BOP and ≥ 2 mm bone-loss (Koldsland, et al. 2010). Data of the present clinical study are in line with previous observations and a reported rate of 9% of the patients with peri-implant disease (Behneke, et al. 2000).

Conclusions

In conclusion, the present study demonstrated 100% survival rates for both two-piece implant systems over the short-term observation period of one year of loading. The relative distances between the bone crest and the flat top of the implant shoulder were shorter, thereby representing higher marginal bone levels in the S2 group for the implant level analysis and higher for the S1 group for the patient level analysis. Radiographically assessed marginal bone level alterations were minimal between loading and the one-year follow-up. Few biological and technical complications occurred. Overall, minimal differences were observed between the two groups. Therefore, within the limitations of this study, both implant systems can be recommended to support fixed implant-borne reconstructions.

Acknowledgements and conflict of interest

This study was fully funded by the Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine, University of Zurich, Zurich, Switzerland. The authors report no conflict of interest with respect to this study.

Figure legends

Table 1. Type of reconstructions on implant- and patient-level for both systems (S1 and S2). FDP = fixed dental prosthesis. ICFDP = implant-supported cantilever fixed dental prosthesis

Table 2. Radiographic data of marginal bone levels (DIB) at implant placement (TP0), insertion of final prosthesis (baseline, TP1), at the one-year follow-up examination (TP2) and changes between time-points (TP1-TP0 and TP2-TP1). Implant- and patient-level analysis with means and standard deviations (SD) and with medians and interquartile range (IQR) for both implant systems (S1 and S2). P-values for the patient-level analysis were calculated with the non-parametric Mann-Whitney test and non-parametric paired Wilcoxon test to assess the influence of time.

Table 3a. Clinical parameters (PPD= probing depth, BOP= bleeding on probing, PCR= plaque control record, REC= recession and KMb= keratinized tissue on the buccal site) for both implant systems (S1 and S2) at insertion of final prosthesis (baseline, TP1) and at the one-year follow-up examination (TP2). Implant-level analysis with means and standard deviations (SD).

Table 3b. Esthetic parameters (Jemt mes= mesial papilla contour measurements, Jemt dist= distal papilla contour measurements, CH = crown height, PHm= mesial papilla height, PHd = distal papilla height, GT= thickness of

the attached gingiva) for both implant systems (S1 and S2) at insertion of final prosthesis (baseline, TP1) and at the one-year follow-up examination (TP2). Implant-level analysis with means and standard deviations (SD).

Table 3c. Clinical parameters (PPD= probing depth, BOP= bleeding on probing, PCR= plaque control record, REC= recession and KMb= keratinized tissue on the buccal site) for both implant systems (S1 and S2) at insertion of final prosthesis (baseline, TP1) and at the one-year follow-up examination (TP2). Patient-level analysis with means and standard deviations (SD). P-values calculated with non-parametric Mann-Whitney test and non-parametric paired Wilcoxon test to asses the influence of time.

Table 3d. Esthetic parameters (Jemt mes= mesial papilla contour measurements, Jemt dist= distal papilla contour measurements, CH = crown height, PHm= mesial papilla hight, PHd = distal papilla hight, GT= thickness of the attached gingival) for both implant systems (S1 and S2) at insertion of final prosthesis (baseline, TP1) and at the one-year follow-up examination (TP2). Patient-level analysis with means and standard deviations (SD). P-values calculated with non-parametric Mann-Whitney test and non-parametric paired Wilcoxon test to assess the influence of time.

Conflict of interest:

The authors declare that they have no conflict of interest.

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Tables and Figures

Table1.

	Implant-level		Patient-level	
	S1	**S2**	**S1**	**S2**
single crown	29	13	19	12
splinted single crowns	4	2	2	0
FDPs	13	15	6	8
ICFDPs	8	13	6	11

Table 2.

DIB	**Implant-level**						**Patient-level**								
	S1			**S2**			**S1**				**S2**				
	Mean SD (mm)	Median IQR (mm)	Range (mm) min max	Mean SD (mm)	Median IQR (mm)	Range (mm) min max	Mean SD (mm)	Median IQR (mm)	Range (mm) min max	Paired p-value	Mean SD (mm)	Median IQR (mm)	Range (mm) min max	Paired p-value	p-value
TP0	-1.07 ±0.94	-1.01 ±1.37	-4.01 0.59	-1.21 ±1.13	-1.15 ±1.01	-4.92 0.65	-1.30 ±1.00	-1.37 ±1.15	-4.01 0.59		-1.26 ±1.22	-1.20 ±1.12	-4.92 0.65		0.55
TP1	0.39 ±0.53	0.37 ±0.39	-1.09 2.82	0.21 ±0.40	0.09 ±0.39	-0.42 1.70	0.29 ±0.44	0.36 ±0.44	-1.09 1.00		0.22 ±0.43	0.09 ±0.36	-0.31 1.70		0.028*
Difference TP1 –TP0	1.44 ±0.94	1.37 ±1.54	-0.44 3.50	1.42 ±1.08	1.16 ±1.31	-0.55 0.94	1.58 ±0.93	1.62 ±1.47	-0.44 3.39	<0.001*	1.48 ±1.16	1.16 ±1.34	-0.55 0.70	<0.001*	0.371
TP2	0.49 ±0.62	0.39 ±0.29	-1.22 3.76	0.34 ±0.88	0.15 ±0.39	-0.44 5.23	0.37 ±0.39	0.36 ±0.33	-1.22 0.97		0.39 ±1.02	0.14 ±0.38	-0.44 5.23		0.008*
Difference TP2 –TP1	0.07 ±0.28	0.02 ±0.25	-0.17 4.92	0.13 ±0.75	0.00 ±0.18	-0.48 4.69	0.04 ±0.23	0.01 ±0.26	-0.17 4.92	0.342	0.17 ±0.86	0.00 ±0.13	-0.48 4.69	0.532	0.752

Table 3a.

Implant-level	**PPD**		**BOP**		**PII**		**REC**				**KMb**	
	S1	**S2**	**S1**	**S2**	**S1**	**S2**	**S1**		**S2**		**S1**	**S2**
	Mean SD (mm)	Mean SD (mm)	Mean SD (%)	Mean SD (%)	Mean SD (%)	Mean SD (%)	Mean SD (mm)	Range (mm) min max	Mean SD (mm)	Range (mm) min max	Mean SD (mm)	Mean SD (mm)
TP1	3.09 ±0.55	2.89 ±0.77	25 ±21	24 ±18	5 ±11	7 ±14	0.01 ±0.05	0.00 0.33	0.03 ±0.09	0.00 0.50	2.91 ±1.19	3.09 ±1.48
TP2	3.13 ±0.73	3.07 ±0.61	26 ±20	27 ±23	4 ±10	4 ±10	0.02 ±0.87	0.00 0.50	0.20 ±0.96	0.00 6.00	2.83 ±1.25	3.16 ±1.57
Difference TP2-TP1	0.04 ±0.89	0.19 ±0.98	1 ±23	3 ±26	-1 ±11	- 3 ±15	0.01 ±0.09	-0.17 0.50	0.17 ±0.96	-0.50 6.00	-0.08 ±1.02	0.07 ±0.67

Table 3b.

Implant-level	Jemt mes		Jemt dist		CH		PHm		PHd		GT	
	S1	S2	S1	S2	S1	S2	S1	S2	S1	S2	S1	S2
	Mean SD (0-4)	Mean SD (0-4)	Mean SD (0-4)	Mean SD (0-4)	Mean SD (mm)	Mean SD (mm)	Mean SD (mm)	Mean SD (mm)	Mean SD (mm)	Mean SD (mm)	Mean SD (mm)	Mean SD (mm)
TP1	1.58 ±0.66	1.73 ±0.77	1.47 ±0.64	1.40 ±0.71	9.87 ±1.40	9.77 ±1.86	7.25 ±1.82	7.54 ±1.61	7.30 ±1.45	7.64 ±1.78	3.33 ±1.48	3.10 ±1.34
TP2	1.78 ±0.70	1.92 ±0.76	1.51 ±0.67	1.64 ±0.76	9.79 ±1.62	10.12 ±2.46	7.57 ±2.26	7.65 ±2.54	7.48 ±1.44	7.82 ±2.49	3.26 ±1.36	3.07 ±1.38
Difference TP2-TP1	0.19 ±0.53	0.19 ±1.00	0.03 ±0.48	0.24 ±0.60	-0.06 ±0.89	0.35 ±1.13	0.33 ±1.14	0.11 ±1.82	0.15 ±1.08	0.18 ±1.64	-0.10 ±1.31	0.04 ±1.05

Table 3c.

Patient-level	PPD			BOP			PII			REC					KMb		
	S1	S2		S1	S2		S1	S2		S1		S2			S1	S2	
	Mean SD (mm)	Mean SD (mm)	p-value	Mean SD (%)	Mean SD (%)	p-value	Mean SD (%)	Mean SD (%)	p-value	Mean SD (mm)	Range (mm) min max	Mean SD (mm)	Range (mm) min max	p-value	Mean SD (mm)	Mean SD (mm)	p-value
TP1	3.13 ±0.51	2.83 ±0.88		24 ±22	21 ±18		7 ±13	8 ±15		0.01 ±0.06	0.00 0.33	0.03 ±0.10	0.00 0.50		3.15 ±1.23	3.23 ±1.54	
TP2	3.05 ±0.54	3.01 ±0.59		25 ±20	27 ±25		5 ±12	5 ±11		0.02 ±0.09	0.00 0.50	0.21 ±1.08	0.00 6.00		3.12 ±1.34	3.26 ±1.55	
Difference TP2-TP1	0.09 ±0.82	0.18 ±1.11	0.165	1 ±23	6 ±27	0.477	- 2 ±13	- 3 ±16	0.639	0.01 ±0.09	-0.17 0.50	0.18 ±1.09	-0.50 6.00	0.963	-0.03 ±1.21	0.03 ±0.48	0.165
Paired p-value	0.261	0.393		0.951	0.220		0.842	0.325		0.655		0.916			0.507	0.705	

Table 3d.

Patient-level	Jemt mes			Jemt dist			CH			PHm			PHd			GT		
	S1	S2		S1	S2		S1	S2		S1	S2		S1	S2		S1	S2	
	Mean SD (0-4)	Mean SD (0-4)	p-value	Mean SD (0-4)	Mean SD (0-4)	p-value	Mean SD (mm)	Mean SD (mm)	p-value	Mean SD (mm)	Mean SD (mm)	p-value	Mean SD (mm)	Mean SD (mm)	p-value	Mean SD (mm)	Mean SD (mm)	p-value
TP1	1.72 ±0.68	1.85 ±0.72		1.46 ±0.58	1.32 ±0.75		9.79 ±1.33	9.74 ±1.77		7.13 ±1.88	7.22 ±1.63		7.30 ±1.35	7.74 ±1.97		3.18 ±1.47	3.32 ±1.39	
TP2	1.84 ±0.69	2.00 ±0.73		1.52 ±0.51	1.58 ±0.77		9.88 ±1.49	10.03 ±2.09		7.45 ±2.38	7.63 ±2.26		7.54 ±1.29	8.24 ±2.68		3.26 ±1.35	3.26 ±1.52	
Difference TP2-TP1	0.13 ±0.50	0.15 ±0.66	0.824	0.04 ±0.53	0.26 ±0.56	0.171	0.09 ±0.85	0.29 ±1.01	0.344	0.32 ±1.01	0.41 ±1.55	0.772	0.19 ±1.13	0.50 ±1.66	0.580	-0.08 ±1.02	-0.06 ±0.10	0.689
Paired p-value	0.157	0.248		0.705	0.059		0.694	0.124		0.088	0.229		0.368	0.236		0.696	0.854	